

REMARKS**STATUS OF THE CLAIMS**

Claims 22-52 are pending in the present application. Claims 28, 36, 39-41, 44-45 and 47 are withdrawn from consideration. By virtue of this response, claims 26 and 27 have been cancelled, claims 22-25, 28, 29, 31-47, and 50-52 have been amended, and new claims 53-68 have been added. Accordingly, claims 22-25, 29-35, 37, 38, 42, 43 and 46, 48-68 are currently under consideration.

With respect to all amendments and cancellations, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application. No new matter has been added by the new or amended claims.

GENERAL CONSIDERATIONS

Applicants alert the Examiner to an error on the Office Action Summary of the final Office Action, where the Action is listed as responsive to a communication filed February 16, 2004. Applicants' response to the prior non-final Office Action was filed on December 16, 2004 and not on February 16, 2004.

In numbered paragraph 5 of the final Office Action, the Examiner states that reference 17 on PTO form 1449 filed August 23, 2004 has been crossed out because a European Office Action is inappropriate to be printed on an issued patent. Applicants are unaware of a statute, rule or Manual of Patent Examining Procedure section to support the conclusion that Applicants are prohibited from submitting a European Office Action for the Examiner's consideration. In addition, Applicants have identified issued U.S. Patents with European Office Actions printed thereon. A recently issued example is U.S. Patent No. 6,900,287, issued May 31, 2005, with "Office Action for EP 99 91 7137 dated Oct. 15, 2002" printed thereon. Based on the above, Applicants assert that it is

entirely appropriate to bring a European Office Action to the attention of the Examiner. Accordingly, Applicants have resubmitted the European Office Action for consideration in a supplemental Information Disclosure Statement filed herewith.

CLAIM AMENDMENTS AND ADDITIONS

Claim 22 has been amended to incorporate previously pending claim 26 into the independent claim, to recite a conjugate, and to recite valency platform molecules having certain structural features, such as a valency provided by attachment sites located at termini of the valency platform molecule and wherein the number of branching groups pre-determines the number of attachment sites. Support for the amendment to claim 22 may be found, e.g., in originally presented claims 22 and 26 and in the application as filed, e.g., on page 17, lines 20-24; on page 19, line 14 to page 20, line 3 and in the examples. **Claims 23-25, 28, 31-47, and 50-52** have been amended to recite a conjugate in accordance with amended claim 22.

Claim 23 has been amended to reintroduce the triamine moiety as originally presented. Support for the amendment to claim 23 can be found in originally presented claim 23 and on page 19, lines 17-19 of the application as filed.

Claim 28 has been amended to recite the plural form of analog molecules.

Claim 29 has been amended to recite a pharmaceutically acceptable composition.

Claims 31-35 have been amended to recite valency platform molecules comprising certain moieties. This amendment makes clear that the recited chemical entity (e.g., polyethylene glycol) is present as a moiety of the chemically defined valency platform molecule.

Newly added claims 53-68 are dependent from previously presented claims.

Claims 53-59 recite each of the analog molecules listed in Markush form in claim 22 as individual claims. Support for these claims may be found, e.g., in originally presented claims 22 and 26.

Claim 60 recites a polyethylene glycol moiety of a stated molecular weight range. Support for this claim may be found, e.g., on page 20, lines 7-9 of the application as filed.

Claims 61-65 recite compositions comprising conjugates comprising a linking group and methods of making the same. Support for these claims may be found, e.g., at page 28, lines 24-26 and the descriptions that follow; Example 3 on page 79; Table I on page 80 and in the Examples as filed.

Claim 66 recites a certain valency platform molecule. Support for this claim may be found, e.g., in Reaction Scheme 1 on page 31 and the accompanying text.

RESTRICTION REQUIREMENT

Applicants appreciate the Examiner's willingness to reconsider the restriction requirement as stated in paragraph 6 of the final Office Action and as confirmed by the Examiner in a telephone conversation with Applicants' representative on September 21, 2005. Applicants respectfully refer the Examiner to the detailed response to restriction requirement mailed March 26, 2004, in which Applicants' representatives outlined the basis for traversal of the restriction requirement, including (1) the groupings do not conform to the patent statute; (2) the Office Action fails to establish a *prima facie* showing for the restriction; (3) the groupings are highly unreasonable; and (4) linking claims are present that require all claims to be examined should a linking claim be allowed. Applicants urge and respectfully request the Examiner to withdraw the restriction requirement for the reasons of record.

REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 22-27, 29-35, 37-38, 42-43 and 46 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,060,056.

In the December 16, 2004 response to non-final Office Action, Applicants amended claim 23 and stated that U.S. Patent No. 6,060,056 is not available as a 35 U.S.C. §102(e) reference against claims 22-27, 29-35, 37-38, 42-43 and 46 because the reference is not “by another.” By virtue of this response, Applicants have amended claim 23 to reintroduce the term “triamine.” Applicants’ representatives have subsequently concluded that the inventorship listed in the December 16, 2004 response to non-final Office Action was inadvertently in error. Applicants will address inventorship correction as needed.

Claims 26 and 27 have been cancelled, rendering the rejection with respect to those claim moot. The 35 U.S.C. §102(e) rejection with respect to claims 22-25, 29-35, 37-38, 42-43 and 46 is discussed below.

Applicants respectfully traverse the Examiner’s 35 U.S.C. § 102(e) rejection over U.S. Patent No. 6,060,056 (“the ‘056 patent”) on the basis that the subject matter relied on in making the rejection is not entitled to the priority date of February 8, 1991 and is therefore not available to support the Examiner’s 35 U.S.C. § 102(e) rejection of claims 22-25, 29-35, 37-38, 42-43 and 46.

The ‘056 patent was filed on September 8, 1993 as a continuation-in-part of U.S. Application Serial No. 07/652,648, which issued as U.S. Patent No. 5,268,454 (“the ‘454 patent”). The conjugates and valency platform molecules relied on by the Examiner in making the present rejection are not disclosed in or supported by the ‘454 patent. In contrast to conjugates such as those shown in Figure 11 of the ‘056 patent, the ‘454 patent discloses conjugates of analogs coupled to nonimmunogenic polymeric carriers, such as polyethylene glycol, poly-D-lysine, copolymers of D-glutamic acid and D-lysine, and immunoglobulins (See, e.g., column 5, lines 1-17 of the ‘454 patent).

The present rejection of claims 22-25, 29-35, 37-38, 42-43 and 46 over the '056 patent is not proper because the subject matter relied on in making the rejection has an effective filing date of September 8, 2003 (the filing date of the '056 patent) and not February 8, 1991 (the filing date of the '454 patent). Accordingly, the '056 patent does not support the Examiner's 35 U.S.C. §102(e) rejection of the presently rejected claims.

Applicants respectfully request the Examiner to withdraw the 35 U.S.C. § 102(e) rejection of claims 22-25, 27, 29-35, 37-38, 42-43 and 46 over U.S. Patent No. 6,060,056.

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 22-27, 29-35, 37-38 42-24, 46 and 48-51 are rejected as allegedly being unpatentable over claims 1, 3, 6, 7, 9, 10, and 12-18 of U.S. Patent No. 6,060,056 under the doctrine of obviousness-type double patenting. Applicants respectfully traverse this rejection.

The claims in the present application recite conjugates formable by the conjugation of at least two analog molecules and a chemically defined valency platform molecule comprising certain structural features. Additional features to further clarify and define the valency platform molecules have been added by amendment. The following discussion addresses the rejection as it applies to the claims previously under examination and how it may apply to the amended claims, although Applicants do not believe that such a rejection would be proper.

The claims of the '056 patent do not suggest conjugates with the certain structural characteristics recited in the instant claims. In particular, there is no suggestion in the claims of the '056 patent of a conjugate formable by the conjugation of at least two analog molecules to a chemically defined valency platform molecule comprising branching groups, a defined valency and attachment sites at particular locations. The structural characteristics recited in the present claims render claims 22-26, 27, 29-35, 37-38 42-24, 46 and 48-51 patentably distinct from claims 1, 3, 6, 7, 9, 10, and 12-18 of the '056 patent.

The Examiner's basis for this rejection appears to be summarized on page 8 of the Office Action, which states that the present claims are a "species" that anticipate the "generic" conjugate of the '056 patent. Throughout the detailed explanation of the rejection, the Examiner refers to the claims of the '056 patent as a "genus" that would "include" the instant application's "species" claims. The Examiner contends that issuance of the presently pending "species" claims would anticipate the composition claims of the '056 patent, presumably finding that this is a basis for establishing obviousness-type double patenting. Applicants traverse this rejection on the basis that (1) the rejection is premised on the incorrect application of the law, and (2) the claims of the '056 patent do not render the instant claims obvious because the structural characteristics of the instant claims render them patentably distinct from the claims of the '056 patent.

When determining whether claims in an issued patent render obvious the claims in a pending application, the differences between the inventions defined by the conflicting claims should be determined, followed by an analysis of why a person of ordinary skill in the art would conclude that the invention defined in the claim of the application is an obvious variation of the invention defined in the claim in the patent. MPEP § 804. Importantly, claims under examination cannot be rejected for obviousness-type double patenting under the rationale that the examined claims are dominated by earlier issued patent claims. *Id.* No improvement patents could ever issue to anyone other than the patentee if the law was otherwise. As stated in section 804 of the Manual of Patenting Examining Procedures:

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself; i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. *In re Sarett*, 140 USPQ 474, 482 (CCPA 1964); *In re Kaplan*, 229 USPQ 678, 681 (Fed. Cir. 1986).

The current rejection is clearly a case in which the Examiner has confused domination with double patenting and appears to consider dominance alone as a basis for making this rejection.

In making the rejection, the Examiner does not explain the differences between the inventions defined by the conflicting claims. Rather, the Examiner has reproduced the basic structure of the claims and has labeled them either “genus” or “species.” The Examiner does not offer an analysis of why a person of ordinary skill in the art would conclude that the invention defined in the rejected claims of the application is an obvious variation of the invention defined in the claims of the ‘056 patent. The Examiner bases the present rejection on the rationale that the later set of claims (*i.e.*, the claims in the pending application) would *anticipate* the earlier-issued claims (*i.e.*, the claims of the ‘056 patent). However, as noted above, the correct comparison for an obviousness-type double patenting rejection is to determine if the later set of claims is *obvious* in view of the earlier-issued claims. Although the Examiner has set forth reasons why the rejected claims in the present application are dominated by the claims in the ‘056 patent, this has nothing to do with establishing a *prima facie* case for obviousness-type doubling patenting.

In making the present rejection, the Examiner has also stated that the polyethylene glycol recitation in claims 31-32 is the same as that of claims 10, 12 and 13 of the ‘056 patent having branch groups such as D-lysine residues. However, the chemically defined platform molecule of claims reciting branch groups and attachment sites at particular locations is not “the same as” a polymer of D-lysine, which does not have branching groups in the same manner as the instant claims and does not have attachment sites at particular locations or the homogenous molecular weight as recited. Further, the newly amended claims are also not the same as a claim reciting D-lysine because the valency platform molecule of the present claims recites attachment sites at termini of the valency platform molecule and a valency that is predetermined by the number of branching groups.

The present rejection is based in an incorrect rationale that later claims which anticipate earlier-issued claims form the basis for an obviousness-type double patenting rejection. This notion is clearly rejected by case law and the MPEP. Under the correct application of the law, claims 22-27, 29-35, 37-38 42-24, 46 and 48-51 are not unpatentable over claims 1, 3, 6, 7, 9, 10, and 12-18 of the ‘056 patent because the structural features in the rejected claims render them patentably distinct from the claims of the ‘056 patent. Accordingly, Applicants respectfully request the Examiner to

withdraw the obvious double patenting rejection of claims 22-25, 27, 29-35, 37-38 42-24, 46 and 48-51 over claims 1, 3, 6, 7, 9, 10, and 12-18 of the '056 patent.

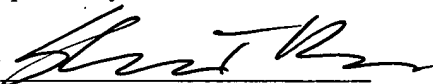
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 252312005706. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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